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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,464	03/28/2001	Martin Friede	B45070-1	1150

7590 07/17/2006
GLAXOSMITHKLINE
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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/819,464

Applicant(s)

FRIEDE ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-94 is/are pending in the application.
4a) Of the above claim(s) 85-93 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 74-84 and 94 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 28 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 74-94 are currently pending in the application.
2. In the prior action, the Final Action mailed on February 22, 2006, claims 74-94 were pending; with claims 74-84 and 94 rejected, and claims 85-93 withdrawn as to non-elected inventions.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's Response filed on June 26, 2006 has been entered.

In the Response, the Applicant presents an additional argument in traversal of the rejections of record.

4. Claims 74-84 and 94 are under consideration.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **(Prior Rejection- Maintained)** Claims 74-76, 78, 80, and 82-84 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lipford (Vaccine 12: 72-80) in view of the teachings of Kensil (U.S. 5,583,112). These claims describe compositions comprising an antigen, the saponin

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QS-21, and sterol (preferably cholesterol) in excess by weight to the saponin of 1:2 to 1:100. The Applicant traverses the rejection on the basis that, if Quil A is replaced with QS21, the resulting compositions would not fall within the scope of the pending claims. This argument is not found persuasive.

The Applicant's argument is based on the assumption that the QS21 would be substituted for the crude Quil A extract only to the extent that the QS21 is present in the crude extract, and that no corresponding reduction would be made to the amount of sterol used. Such is not the case. Rather, those in the art would instead be motivated to use a reduced amount of sterol equivalent to the requisite dosage of QS21. I.e., those of ordinary skill in the art would be motivated to use the same ratio of QS21 to sterol as they would have used to for Quil A to sterol. This is because, while the art teaches that a reduced quantity of QS21 is required for adjuvant activity, there is no corresponding teaching suggesting the use of reduced ration of the sterol component relative to the saponin used. Thus, the Applicant's argument is not found persuasive.

Further, even if the Applicant's argument regarding the reduction of QS21 without a corresponding reduction of sterol was accepted, those of ordinary skill in the art would not use an amount of QS21 equal to approximately 3.7% the amount of Quil A, but would actually use approximately half the amount of Quil A used. This is because Kensil teaches that the QS21 saponin achieves the same adjuvanting effects as Quil A at approximately half the dose, and not at 3.7% of the dose. Cf., column 5 lines 20-29 and column 6 lines 30-36. Thus, one would replace the .4 mg of Quil A with .2 mg of QS21, resulting in a 1:25 weight/weight ratio of QS21 to sterol, not a 1:337 ratio as asserted by the Applicant.

For the reasons above, and the reasons of record, the rejection is maintained.

7. **(Prior Rejection- Maintained)** Claims 77, 79, and 81 were rejected under 35 U.S.C. 103(a) as being unpatentable over either Lipford in view of Kensil as applied against claims 74-76, 78, 80, 82-84, and 94 above, and further in view of Prieels et al. (WO 94/00153). Dependent claims 77, 79, and 81 describe a composition as claimed above wherein the adjuvant formulation also comprises alum salts and/or 3 De-O-acylated monophosphoryl lipid A. The Applicant traverses this on the same grounds as argued with respect to the rejection over Lipford and Kensil above. The rejection is therefore maintained for the reasons above, and the reasons of record.

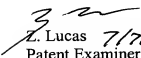
Conclusion

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


L. Lucas
Patent Examiner

7/7/06